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EXPRESS MAIL NO: EV 456 933 684 US**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of: *Parkin, et al.* Confirmation No.: 4526
Serial No.: 10/612,600 Art Unit: 1646
Filed: July 1, 2003 Examiner: To be Assigned
For: COMPOSITIONS AND METHODS Attorney Docket No.: 11068-015-999
FOR DETERMINING THE
SUSCEPTIBILITY OF A
PATHOGENIC VIRUS TO
PROTEASE INHIBITORS

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

1. Enclosures accompanying this Information Disclosure Statement are:
 - 1a. ☒ A list of all patents, publications, applications, or other information submitted for consideration by the office.
 - 1b. A legible copy of :
 - ☒ Each U.S. patent application publication and U.S. and foreign patent;
 - ☒ Each publication or that portion which caused it to be listed on the PTO-1449;
 - ☐ For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion;
 - ☐ all other information or portion which caused it to be listed on the PTO-1449.
 - 1c. ☒ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report.
 - 1d. ☐ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications.
2. ☒ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b);
 - ☐ Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);

- ☐ Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;
- ☒ Before the mailing of the first Office action on the merits;
- ☐ Before the mailing of a first Office action after the filing of a request for continued examination under §1.114.

3. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R. §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.

(Check either Item 3a or 3b)

- 3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.
- 3b. ☐ The \$180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:
☐ enclosed
☐ to be charged to Jones Day Deposit Account No. 503013.

(Item 3b to be checked if any reference known for more than 3 months)

4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.

The \$180.00 fee set forth in 37 C.F.R. §1.17(p) is:

- ☐ enclosed.
- ☐ to be charged to Jones Day Deposit Account No. 503013.

The Certification Statement in Item 5 below is applicable.

5. ☐ Certification Statement (applicable if Item 3a or Item 4 is checked)

(Check either Item 5a or 5b)

- 5a. ☐ In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- 5b. ☐ In accordance with 37 C.F.R. §1.97(e)(2), it is certified that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was known by any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.
6. ☐ This application is a continuation application under 37 C.F.R. §1.60 or §1.53(b) or (d).

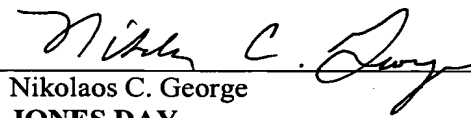
(Check appropriate Items 6a, 6b and/or 6c)

- 6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently filed herewith.

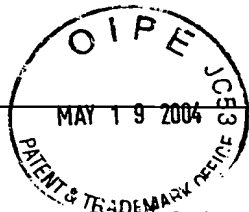
- 6b. ☐ Copies of publications listed on Form PTO-1449 from prior application Serial No. , filed on , of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).
- 6c. ☐ Copies of the publications listed on Form PTO-1449 were not previously cited in prior application Serial No. , filed on , and are provided herewith.
7. ☐ This is a Supplemental Information Disclosure Statement. (Check Item 7a)
- 7a. ☐ This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on . A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on .
8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:
- (Check Item 8a, 8b, or 8c)
- 8a. ☐ satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.
- 8b. ☐ set forth in the application.
- 8c. ☐ enclosed as an attachment hereto.
9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Jones Day Deposit Account No. 503013.
10. ☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability nor a representation that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

Respectfully submitted,

Date: May 19, 2004


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LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)

ATTY DOCKET NO.

11068-015-999

APPLICATION NO

10/612,600

APPLICANT

Parkin et al.

FILING DATE

July 1, 2003

GROUP

1646

U.S. PATENT DOCUMENTS

| *EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
|----------------------|-----|-----------------|----------|------------------|-------|----------|-------------------------------|
| | A01 | 5,436,131 | 7/25/95 | Condra et al. | | | |
| | A02 | 5,837,464 | 11/17/98 | Capon et al. | | | |
| | A03 | 6,033,902 | 3/7/00 | Haseltine et al. | | | |
| | A04 | 6,103,462 | 8/15/00 | Paulous et al. | | | |
| | A05 | 6,242,187 | 6/5/01 | Capon et al. | | | |

FOREIGN PATENT DOCUMENTS

| | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION | |
|--|-----|---|--------|---------|-------|----------|-------------|----|
| | | | | | | | YES | NO |
| | A06 | WO99/67427 | 6/99 | PCT | | | | |
| | A07 | Int'l Search Report for PCT/US03/21335 | 5/3/04 | PCT | | | | |

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

| | |
|-----|---|
| A08 | Genbank Accession Number P12497 POL Polypeptide (2004) |
| A09 | Genbank Accession Number AF324493 HIV-1 vector pNL4....[gi:12831134] (2001). |
| A10 | Gervais, et al., (1997), "A New Reporter Cell Line to Monitor HIV Infection and Drug Susceptibility <i>in Vitro</i> ," <i>Proc. Natl. Acad. Sci. USA</i> , 94: 4653-4658. |
| A11 | Gunthard, et al., (1998), "Comparative Performance of High-Density Oligonucleotide Sequencing and Dideoxynucleotide Sequencing of HIV Type 1 <i>pol</i> From Clinical Samples," <i>Aids Research and Human Retroviruses</i> , 14(10): 869-876. |
| A12 | Herrmann, et al., (1997), "A Working Hypotheses-Virus Resistance Development As An Indicator of Specific Antiviral Activity," <i>Ann. NY Acad Sciences</i> , 284: 632-637. |
| A13 | Hertogs, et al., (1998), "A Rapid Method for Simultaneous Detection of Phenotypic Resistance to Inhibitors of Protease and Reverse Transcriptase in Recombinant Human Immunodeficiency Virus Type 1 Isolates From Patients Treated with Antiretroviral Drugs," <i>Antimicrobial Agents and Chemotherapy</i> , 42(2): 269-276. |
| A14 | Hirsch, et al., (2000), "Antiretroviral Drug Resistance Testing in Adult HIV-1 Infection" <i>JAMA</i> , 283(18): 2417-26. |
| A15 | Petropoulos, et al., (2000), "A Novel Phenotypic Drug Susceptibility Assay For Human Immunodeficiency Virus Type 1," <i>Antimicrobial Agents and Chemotherapy</i> , 44(4): 920-928. |
| A16 | Race, et al., (1999), "Analysis of HIV Cross-Resistance to Protease Inhibitors Using A Rapid Single-Cycle Recombinant Virus Assay For Patients Failing On Combination Therapies," <i>AIDS</i> , 13(15): 2061-2068. |
| A17 | Schuurman, et al., (1999), "Worldwide Evaluation of DNA Sequencing Approaches for Identification of Drug Resistance Mutations in the Human Immunodeficiency Virus Type 1 Reverse Transcriptase," <i>Journal of Clinical Microbiology</i> , 37(7): 2291-2296. |
| A18 | Shi, et al., (1997), "A Recombinant Retroviral System for Rapid In Vivo Analysis of Human Immunodeficiency Virus Type 1 Susceptibility to reverse Transcriptase Inhibitors," <i>Antimicrobial Agents and Chemotherapy</i> , 41(12): 2781-85. |
| A19 | Ziermann, et al., (2000), "A Mutation in Human Immunodeficiency Virus Type 1 Protease, N88S, That Causes In Vitro Hypersensitivity to Amprenavir," <i>Journal of Virology</i> , 74(9): 4414-4419. |

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.